DOUBLE BALLOON THROMBECTOMY CATHETER

RELATED APPLICATIONS

This application is a continuation-in-part of pending Patent Cooperation Treaty Application No. PCT/US00/41355 filed October 20, 2000, which designates the United States, priority from the filing date of which is hereby claimed under 35 U.S.C. § 120, which PCT application claims the benefit of U.S. Provisional Patent Applications No. 60/214,331 filed June 27, 2000, and No. 60/161,124 filed October 22, 1999, the benefit of which is hereby claimed under 35 U.S.C. § 119.

BACKGROUND/FIELD OF THE INVENTION

This invention relates to thrombectomy apparatus and procedures of the type generally disclosed in published Patent Cooperation Treaty patent application PCT/US98/15156.

SUMMARY OF THE INVENTION

In the course of a thrombectomy procedure, a clot is purged from the graft. Subsequently, the anastomoses are unplugged using two different types of balloons, preferably an angioplasty balloon for the venous side and a soft, compliant latex balloon for the arterial side. Both balloons are preferably positioned on a common catheter.

A catheter is used to deliver the wire for the dialysis thrombectomy procedure. The invention embraces the placement of the two balloons, namely, the preferably angioplasty balloon for the venous side, and preferably the soft, compliant balloon for the arterial side, on the delivery catheter.

In the course of practicing the method aspect of the invention and going forward with the thrombectomy procedure, the attending physician preferably proceeds to the venous side first, since blood endeavors to flow from the artery side to the vein side. Any blockage at the artery side means less blood flow through the graft, thereby facilitating opening of blockage or unplugging of the venous side. Typically, plaque to be cleared at the venous side is stronger and tougher than any plaque at the artery side. Accordingly, a tough angioplasty balloon, typically formed of a synthetic material, such as PET, is preferably used to unblock the venous side.

Plaque at the arterial side is generally not as hard, with a platelet plug often being encountered at the arterial side. The platelet plug is desirably pulled through the junction of the artery and the graft in order to unplug the arterial side.

In another aspect, this invention provides preferably disposable apparatus for performing mechanical thrombectomy cleansing of dialysis grafts where the apparatus preferably includes an axially-elongated catheter preferably having at least three axially-extending fluid communication passages therewithin, where a first one of the passages preferably has a rounded cross-section for free axial travel therealong of a guide wire inserted thereinto. In this aspect of the invention, the first balloon is desirably positioned along the exterior of the catheter proximate the first catheter end, with the interior of the first balloon being in fluid communication with a second one of the passageways. The first balloon, when inflated, is preferably generally spherical and positioned about the catheter so that the catheter defines an axis of the spherical balloon shape. The catheter desirably passes through the interior of the balloon when the first balloon is inflated.

In this aspect of the invention, a second balloon is desirably positioned along the exterior of the catheter inboard of the first balloon relative to the first catheter, with the interior of the second balloon being in fluid communication with a third

passageway. The second balloon when inflated desirably has an axially elongated generally cylindrical central portion and generally conical end portions, with the cylindrical and conical portions of the balloon being symmetrically positioned about the catheter. The catheter desirably passes through the interior of the second balloon when the second balloon is inflated. The catheter preferably further defines the axis of the cylindrical and conically-shaped portions of the balloon.

In this aspect of the invention, the catheter desirably further includes a pair of inflation ports which respectively communicate with the second and third passageways proximate the second end of the catheter. The passageways are preferably adapted for individual connectable communication with the source of pressurized gas for selectably inflating the first and second balloons by supply of pressurized gas thereto via the second and third passageways in the catheter.

The first balloon is desirably made of a compliant material, such as latex or polyurethane. The second balloon is desirably made of a substantially noncompliant material, such as PET or some other tough material.

The catheter exterior is desirably round, but may be other shapes or asymmetrical.

The invention further embraces the inclusion of radiopaque markers, preferably in the form of bands, on the catheter to facilitate imaging during the thrombectomy cleansing of dialysis grafts. The radiopaque markers are preferably positioned on the catheter to be within the interior of the respective balloons when the balloons are inflated.

In another aspect of the invention, an angioplasty balloon may be used for the arterial side of the graft and a soft "Fogarty style" latex balloon used for the venous side. Both balloons are preferably used on the same catheter. A clot is purged from a dialysis graft and then the anastomoses are unplugged by using the balloons, which are desirably of the two differing types.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an isometric view in schematic form of a preferred double balloon thrombectomy catheter manifesting aspects of the invention;

FIGURE 2 is an enlarged schematic isometric view of the preferred double balloon thrombectomy catheter illustrated in FIGURE 1 showing the two balloons in larger form with radiopaque markers in place on the catheter to facilitate imaging;

FIGURE 3 is a sectional view of the tubular portion of the double balloon thrombectomy catheter illustrated in FIGURES 1 and 2 taken at lines and arrows 3-3 in FIGURE 1;

FIGURE 4 is a schematic side view of another from of a double balloon thrombectomy catheter manifesting aspects of the invention; and

FIGURE 5 is a sectional view of the double balloon thrombectomy catheter illustrated in FIGURE 4 taken at lines and arrows 5-5 in FIGURE 4.

DESCRIPTION OF THE PREFERRED EMBODIMENTS AND BEST MODE KNOWN FOR PRACTICING THE INVENTION

When a dialysis graft is to be cleaned, blood flows through the dialysis graft from the arterial side to the vein side. Typically, the graft fills with clotting material as time passes and must be cleaned periodically in order for subsequent dialysis procedures to be completed successfully.

When dialysis grafts are cleaned, the loosened clotting material is desirably broken up at a location well upstream of that at which loosened particles of clotting material would flow downstream to the lungs. Accordingly, once the graft itself is cleaned, for example, using the approach and apparatus disclosed in the published PCT patent application referenced above, the juncture of the graft with the vein is desirably cleaned prior to cleaning the juncture of the graft with the artery. This is desirable because if the artery side was to be cleaned initially, this would increase the risk of loosened particles of clotting matter being released into the venous system.

When the venous anastomosis shows signs of narrowing, a physician or other attending health professional might opt to perform angioplasty on the venous side. Normally, an angioplasty balloon is used to unplug juncture of the graft and the vein. Material gathering at the juncture of the graft and the vein tends to be plaque-like and is difficult to remove. Hence, a high-strength angioplasty balloon is preferably used for the graft-vein juncture cleaning procedure.

When the cleaning procedure is done at the juncture of the artery and the graft, in practicing the invention most often the physician or attending health care professional preferably uses a latex or other soft balloon. This is desirably accomplished by inserting a wire through the clotting material at the artery-graft juncture. The clotting material at the artery-graft juncture consists mostly of platelets. Once the wire is inserted, from the graft through the platelets and into the artery, the latex balloon is inflated. The platelet plug is then pulled out of position at the juncture of the artery and the graft. This is accomplished by inflating the latex balloon positioned within the artery and then pulling the balloon against the platelet plug and into the graft; this is performed after the balloon has passed through the platelet plug in an uninflated condition. As a result, the platelet plug and clotting material are removed at the same time, sometimes permitting the clotting material and the platelet plug to be removed from the graft without an incision.

The conventional method of clearing the graft involves putting a thrombectomy device into the graft downstream of the arterial stenosis and breaking up the occluding matter. The device is then removed from the graft and reinserted upstream of the venous stenosis to ablate material in the direction of the arterial stenosis. Next the thrombectomy device is removed and a catheter with an angioplasty balloon on it is inserted into the graft to expand or unplug the venous stenosis. This catheter is then removed and a catheter with a compliant balloon is inserted into the graft to expand or unplug the arterial stenosis.

The number of times catheters must be removed and inserted into the graft increases the duration and/or complexity of the procedure and may weaken the graft due to the number of punctures that must be made in it.

The present invention simplifies the procedure used to clear dialysis grafts by placing balloons of different pressure ratings or strengths on the same catheter.

Referring to the drawings, a double balloon thrombectomy catheter according to one embodiment of the present invention is designated generally 10 and includes a catheter designated generally 12. Within catheter 12 are a major internal conduit designated generally 14 and secondary and tertiary internal conduits designated 16

and 26, respectively, for supply of liquid to the angioplasty or substantially noncompliant balloon and a latex or substantially compliant balloon, respectively.

An angioplasty balloon designated generally 18 is mounted on the exterior of catheter 10. The interior of angioplasty balloon 18 communicates in a liquid-tight relationship with secondary internal conduit 16 within catheter 12 in order that angioplasty balloon 18 may be inflated by supply of pressurized liquid thereto via secondary internal conduit 16.

Double balloon thrombectomy catheter 10 further includes a balloon 20 made of a compliant material such as latex or polyurethane positioned as illustrated in the drawings on the exterior of catheter 12. Similarly to the balloon 18, the balloon 20 is positioned to communicate with the interior of tertiary internal conduit 26 in order that pressurized liquid may flow through tertiary internal conduit 26 and inflate the balloon 20. Alternatively, the balloon may be filled with a suitable gas, such as carbon dioxide.

A rotatable thrombectomy wire 22 preferably having a J-shaped tip designated generally 24 is slidably resident within major internal conduit 14. Wire 22 may be advanced out of a distal end 32 of major internal conduit 14 within catheter 12 to perform thrombectomy procedures as described in published Patent Cooperation Treaty patent application PCT/US98/15156 identified above.

A connection port 28 is provided facilitating supply of pressurized liquid to secondary internal conduit 16. Similarly, another connection port 30 is supplied for furnishing pressurized liquid to tertiary internal conduit 26. Connection ports 28, 30, are preferably at the proximate end 34 of catheter 12, which is opposite distal end 32 of catheter 12 from which wire 22 emerges to perform the thrombectomy procedure.

Angioplasty balloon 18 is preferably configured with a cylindrical central portion designated generally 36 and respective conical end portions each designated 38 as illustrated in the drawings.

While the invention has been described with reference to use of a latex or polyurethane balloon to remove the platelet plug anastomosis at the artery-graft juncture, the balloon may alternatively be made of other similar soft, compliant

materials such as polyisoprene, which is a synthetic latex substitute and is well tolerated by persons who are latex intolerant.

Desirably, the angioplasty balloon is a PET or other semi- or noncompliant material capable of withstanding up to twenty (20) or more atmospheres of pressure. Hence, the angioplasty balloon can be inflated to a very high pressure and significant force may be generated with the balloon is inflated to press against the plaque material and thereby open a passageway through the plaque material at the graft-vein juncture.

The angioplasty balloon 18 desirably has a "rewrap" characteristic, so that the balloon rewraps tightly about itself when deflated, to ease insertion and removal of the balloon through introductory sheaths.

Optionally and desirably radiopaque markers, most desirably in the form of marker bands 21, 31, may be provided, preferably on the exterior of catheter 10. These radiopaque markers are desirably provided positioned on catheter 10 so that the marker bands 21, 31, are within the interior of the balloons 18 and 20, respectively, when those balloons are inflated in the manner illustrated in FIGURE 2. However, positioning of the radiopaque markers is not limited to that illustrated in FIGURE 2; the radiopaque markers need not be within one or both of the balloons when the balloons are inflated. So long as the attending physician knows the location of the radiopaque markers vis-à-vis that of the balloons, the angioplasty procedure may go forward with the balloon-carrying catheter being guided radiographically.

While the invention has been described as preferably embracing an angioplasty balloon and a softer latex balloon preferably mounted on a common catheter, the position of the balloons may be reversed from that illustrated in FIGURE 2, the balloons may be differently configured from what is illustrated in FIGURE 2, two balloons of the same type may be used on the catheter, and the like. Similarly, although the balloon 18 is referred to as an angioplasty balloon, other balloon styles that are capable of withstanding pressure required to expand a venous side stenosis could be used. Similarly, the compliant balloon 20 can be any balloon that is strong enough to clear an arterial side blockage.

With the present invention, a physician can use a single catheter to perform a dialysis graft thrombectomy procedure.

A catheter having at least two balloons as described above is inserted into the graft preferably at a point where the catheter can be redirected toward the venous stenosis or the arterial stenosis without removing the catheter from the graft. In one embodiment of the invention, the catheter is inserted into the approximate midpoint of a "U-shaped" dialysis graft. The clotting material in the graft is then removed in the direction of the stenosis at each end of the graft (in either order) using a thrombectomy device placed in the large lumen of the catheter, run over the guide wire, or by using the guide wire itself, such as by rotating the guide wire.

Next, the high pressure balloon is used to expand the stenosis at the venous junction. Finally, the low pressure compliant balloon is used to pull the platelet plug from the arterial junction.

Finally, the dual catheter is not limited to only clearing dialysis grafts. The catheter could be used in any procedure where balloons of different compliancies were previously used on different catheters.

While the present invention has been described with respect to its currently preferred embodiment, it will be appreciated that changes could be made without departing from the scope of the invention. Therefore, the scope of the invention is to be determined solely from the following claims and equivalents thereof.